

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION**

JACLYN BJORKLUND,

Plaintiff,

v.

NOVO NORDISK A/S, NOVO NORDISK
NORTH AMERICA OPERATIONS A/S,
NOVO NORDISK US HOLDINGS INC.,
NOVO NORDISK US COMMERCIAL
HOLDINGS INC., NOVO NORDISK INC.,
NOVO NORDISK RESEARCH CENTER
SEATTLE, INC., NOVO NORDISK
PHARMACEUTICAL INDUSTRIES LP,
and ELI LILLY AND COMPANY,

Defendants.

Case No. 2:23-cv-01020

Judge James D. Cain, Jr.

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, JACLYN BJORKLUND, by her attorneys, MORGAN & MORGAN, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides, which is Louisiana.

2. This Court has personal jurisdiction over Defendants, consistent with the United States Constitution and LA R.S. 13:3201 (Louisiana's "long arm" statute), as Plaintiff's claims arise out of Defendants' transaction of business and the tortious acts within the State of Louisiana,

and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of Louisiana unrelated to Plaintiff's claims.

NATURE OF THE CASE

3. This is an action for damages suffered by Plaintiff, JACLYN BJORKLUND, who was severely injured as a result of her use of Ozempic and Mounjaro, two injectable prescription medications that are used to control blood sugar in adults with type 2 diabetes.

4. Ozempic is also known as semaglutide. Ozempic works by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.

5. Mounjaro is also known as tirzepatide. Mounjaro works by targeting the body's receptors for GIP (glucose-dependent insulintropic polypeptide) and GLP-1 (glucagon-like peptide-1).

6. Ozempic and Mounjaro belong to a class of drugs called GLP-1 receptor agonists ("GLP-1 RAs").

7. Defendants acknowledge that gastrointestinal events are well known side effects of the GLP-1 class. However, Defendants have downplayed the severity of the gastrointestinal events caused by Ozempic and Mounjaro, never, for example, warning of the risk of gastroparesis ("paralyzed stomach").¹

8. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach's motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal

¹ Mounjaro's label mentions gastroparesis without warning of the risk; rather, it states that Mounjaro "has not been studied" in patients with gastroparesis or other severe gastrointestinal disease, "and is therefore not recommended in these patients[.]" and it lists gastroparesis among other medical conditions for patients to discuss with their healthcare providers. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d2d7da5d-ad07-4228-955f-cf7e355e8cc0> (last visited on 8/24/23).

digestion, cause nausea, vomiting, abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, vomiting undigested food, undigested food that hardens and remains in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.²

PARTY PLAINTIFF

9. Plaintiff, JACLYNBJORKLUND, is a citizen of the United States, and is a resident of the State of Louisiana.

10. Plaintiff was born on September 5, 1978.

11. Plaintiff used Ozempic for more than one year stopping use in or around July 2023, at which point she began using Mounjaro.

12. Plaintiff's physician(s) (collectively "prescribing physician(s)") prescribed both Ozempic and Mounjaro that was used by Plaintiff.

13. As a result of using Defendants' Ozempic and Mounjaro, Plaintiff was caused to suffer from gastroparesis and its sequelae and, as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

14. As a result of using Defendants' Ozempic and Mounjaro, Plaintiff was caused to suffer from gastroparesis and its sequelae, which resulted in, for example, severe vomiting, stomach pain, gastrointestinal burning, being hospitalized for stomach issues on several occasions including visits to the emergency room, teeth falling out due to extreme and violent vomiting, requiring additional medications to alleviate her extreme and violent vomiting, and throwing up whole food hours or even days after eating.

15. Plaintiff's injuries were caused by Defendants' Ozempic and Mounjaro.

PARTY DEFENDANTS

² *Gastroparesis*, Mayo Clinic (June 11, 2022) available at <https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787> (last visited on 8/24/23).

16. Defendant Novo Nordisk Inc. is a Delaware corporation with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey.

17. Upon information and belief, Defendant Novo Nordisk Inc. is wholly owned by Defendant Novo Nordisk US Commercial Holdings, Inc.

18. Upon information and belief, Defendant Novo Nordisk US Commercial Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington, Delaware.

19. Upon information and belief, Defendant Novo Nordisk US Commercial Holdings Inc. is wholly owned by Defendant Novo Nordisk US Holdings Inc.

20. Upon information and belief, Defendant Novo Nordisk US Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington, Delaware.

21. Upon information and belief, Defendant Novo Nordisk US Holdings Inc. is wholly owned by Defendant Novo Nordisk A/S.

22. Defendant Novo Nordisk A/S is a public limited liability company organized under the laws of Denmark with a principal place of business in Bagsværd, Denmark.

23. Defendant Novo Nordisk A/S and its subsidiaries and affiliates named herein are collectively referenced as “the Novo Nordisk Defendants.”

24. Defendant Novo Nordisk North America Operations A/S is a company organized under the laws of Denmark with a principal place of business in Bagsværd, Denmark.

25. Novo Nordisk Research Center Seattle, Inc. is a Delaware corporation with a principal place of business at 530 Fairview Ave. N., Seattle, Washington.

26. The Novo Nordisk Defendants' website states that Novo Nordisk's Seattle research center "serves as the foundation of the company's U.S. research and development efforts for diabetes, obesity, liver disease and other therapeutic areas."³

27. Novo Nordisk Pharmaceutical Industries LP is a Delaware corporation with a principal place of business at 3611 and 3612 Powhatan Road, Clayton, North Carolina.

28. The Novo Nordisk Defendants' website states that "the vast majority of our U.S. injectable diabetes and obesity products are produced and packaged at the Clayton aseptic fill-finish site."⁴ Upon information and belief, this refers to Novo Nordisk's manufacturing facility in Clayton, North Carolina, operated by Novo Nordisk Pharmaceutical Industries LP.

29. Defendant Novo Nordisk Pharmaceutical Industries LP is the labeler for Ozempic, and Defendants Novo Nordisk A/S and Novo Nordisk Inc. are identified on Ozempic's label.⁵ The Novo Nordisk Defendants also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic.

30. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

31. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Mounjaro and is identified on its label.⁶

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic and Mounjaro

³ Novo Nordisk website, *Who We Are/Seattle, WA*, available at <https://www.novonordisk-us.com/about/who-we-are/seattle-wa.html> (last visited on 8/24/23).

⁴ Novo Nordisk website, *Who We Are/North Carolina*, available at <https://www.novonordisk-us.com/about/who-we-are/north-carolina.html> (last visited on 8/24/23).

⁵ Ozempic prescribing information, available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a4dec4fd2-6858-4c99-91d4-531f5f2a2d79> (last visited on 8/24/23).

⁶ Mounjaro prescribing information, available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d2d7da5d-ad07-4228-955f-cf7e355c8cc0> (last visited on 8/24/23).

32. On December 5, 2016, the Novo Nordisk Defendants announced submission of a new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement, Defendants represented that in clinical trials “once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea.”⁷

33. On December 5, 2016, Defendant Novo Nordisk Inc. submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.⁸

34. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.⁹ On January 16, 2020, the FDA approved sNDA 209637/S-003.¹⁰

35. On May 28, 2021, Defendant Novo Nordisk Inc. submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009.¹¹

⁷ Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes* (Dec. 5, 2016) available at <https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183> (last visited on 8/24/23).

⁸ FDA Approval Letter for NDA 209637 (Ozempic) available at https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/209637s000ltr.pdf (last visited on 8/24/23).

⁹ *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes*, Cision PR Newswire (March 20, 2019) available at <https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html> (last visited on 8/24/23).

¹⁰ FDA Supplement Approval Letter for NDA 209637/A-003 (Ozempic) available at https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/209637Orig1s003ltr.pdf (last visited on 8/24/23).

¹¹ FDA Supplement Approval Letter for NDA 209637/S-009 (Ozempic) available at https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/209637Orig1s009ltr.pdf (last visited on 8/24/23).

36. On March 28, 2022, the Novo Nordisk Defendants announced the FDA's approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release, Defendants represented Ozempic as having "proven safety" and advertised that "plus it can help many patients lose some weight."¹² As with its prior press releases, Defendants disclosed Important Safety Information and a provided link to the Medication Guide and Prescribing Information, but gastroparesis was not identified as a risk.

37. On September 14, 2021, Eli Lilly submitted NDA 215866 Mounjaro (tirzepatide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On May 13, 2022, the FDA approved NDA 215866.¹³

38. On May 13, 2022, Eli Lilly announced the FDA's approval of NDA 215866 Mounjaro (tirzepatide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. In the press release, Eli Lilly disclosed a safety summary and provided a link to the Medication Guide and Prescribing Information, but gastroparesis was not identified as a risk.

B. Defendants' Marketing and Promotion of Ozempic and Mounjaro

39. On December 5, 2017, the Novo Nordisk Defendants announced the FDA's approval of Ozempic (semaglutide) 0.5 mg or 1 mg injection in a press release stating that: "Novo Nordisk expects to launch OZEMPIC® in the U.S. in Q1 2018, with a goal of ensuring broad insurance coverage and patient access to the product. OZEMPIC® will be priced at parity to current market-leading weekly GLP-1 RAs and will be offered with a savings card program to reduce co-pays for eligible commercially-insured patients. Additionally, as part of the access strategy, Novo

¹² *Novo Nordisk receives FDA approval of higher-dose Ozempic® 2 mg providing increased glycemic control for adults with type 2 diabetes*, Cision PR Newswire (March 28, 2022) available at <https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mg-providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html> (last visited on 8/24/23).

¹³ FDA Approval Letter for NDA 215866 (Mounjaro) available at https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/215866Orig1s000ltr.pdf (last visited on 8/24/23).

Nordisk is working with appropriate health insurance providers to establish innovative contracting solutions.”¹⁴

40. On February 5, 2018, the Novo Nordisk Defendants announced that they had started selling Ozempic in the United States and touted the medication as a “new treatment option[]” that “addresses the concerns and needs of people with diabetes[.]” The Novo Nordisk Defendants offered an “Instant Savings Card to reduce co-pays to as low as \$25 per prescription fill for up to two years.”¹⁵

41. The Novo Nordisk Defendants promoted the safety and sale of Ozempic in the United States on its websites, in press releases, through in-person presentations, through the drug’s label, in print materials, on social media, and through other public outlets.

42. On July 30, 2018, the Novo Nordisk Defendants launched their first television ad for Ozempic to the tune of the 1970s hit pop song “Magic” by Pilot wherein the Novo Nordisk Defendants advertised that “adults lost on average up to 12 pounds” when taking Ozempic, even though it is not a weight loss drug.¹⁶

43. Over the next five years, the Novo Nordisk Defendants spent \$884,000,000 on running television ads in the United States to promote its semaglutide drugs (Ozempic, Wegovy and Rybelsus) with the majority of the spending allocated specifically to advertising Ozempic.¹⁷

¹⁴ *Novo Nordisk Receives FDA Approval of OZEMPIC® (semaglutide) Injection For the Treatment of Adults with Type 2 Diabetes*, Cision PR Newswire (December 05, 2017), available at <https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-ozempic-semaglutide-injection-for-the-treatment-of-adults-with-type-2-diabetes-300567052.html> (last visited on 8/24/23).

¹⁵ *Novo Nordisk Launches Ozempic® and Fiasp®, Expanding Treatment Options for Adults with Diabetes*, Cision PR Newswire (February 05, 2018) available at <https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-300592808.html> (last visited on 8/24/23).

¹⁶ *Ozempic TV Spot, ‘Oh!’*, iSpot.tv (July 30, 2018) available at <https://www.ispot.tv/ad/d6Xz/ozempic-oh> (last visited on 8/24/23).

¹⁷ Ritzaui, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MedWatch (April 26, 2023) available at https://medwatch.com/News/Pharma___Biotech/article15680727.ece (last visited on 8/24/23).

44. On July 6, 2023, it was reported that the Novo Nordisk Defendants had spent \$11,000,000 on food and travel for doctors as part of the Novo Nordisk Defendants' efforts to promote Ozempic.¹⁸

45. As a result of the Novo Nordisk Defendants' advertising and promotion efforts, Ozempic has been widely used throughout the United States. The number of prescriptions filled reached an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.¹⁹ In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.²⁰

46. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,²¹ and currently has over 1.2 billion views.²²

47. On June 15, 2023, a news report was published about the "thousands of weight-loss ads on social media for the drugs Ozempic and Wegovy." And while many of those ads were found to be from online pharmacies, as of June of 2023 the Novo Nordisk Defendants were still running online social-media ads for its semaglutide products despite claiming in May that it would stop running ads due to a shortage of the drug.²³

¹⁸ Zadikian M, Khemlani A (Transcript of Video), *Novo Nordisk spent \$11 million on Ozempic promotion*, Yahoo Finance (July 6, 2023) available at <https://finance.yahoo.com/video/novo-nordisk-spent-11-million-155418308.html> (last visited on 8/24/23).

¹⁹ Choi A, Vu H, *Ozempic prescriptions can be easy to get online. Its popularity for weight loss is hurting those who need it most*, CNN (March 17, 2023) available at <https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/> (last visited on 8/24/23).

²⁰ Gilbert D, *Insurers clamping down on doctors who prescribe Ozempic for weight loss*, The Washington Post (June 12, 2023) available at <https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/> (last visited on 8/24/23).

²¹ Blum D, *What is Ozempic and Why Is It Getting So Much Attention?*, The New York Times (published Nov. 22, 2022, updated July 24, 2023) available at <https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html> (last visited on 8/24/23).

²² <https://www.tiktok.com/tag/ozempic> (last visited on 8/24/23).

²³ Ingram D, *More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook*, NBC News (June 15, 2023) available at <https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602> (last visited on 8/24/23).

48. On July 10, 2023, a global media company declared Ozempic as “2023’s buzziest drug” and one of the “Hottest Brands, disrupting U.S. culture and industry.”²⁴

49. At all relevant times, the Novo Nordisk Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Ozempic.

50. On May 13, 2022, Eli Lilly announced approval of Mounjaro, proclaiming “Mounjaro’s safety ... in a broad range of adults with type 2 diabetes.”²⁵

51. At all relevant times, Eli Lilly was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Mounjaro.

52. On October 6, 2022, Eli Lilly announced that the FDA had “granted Fast Track designation for the investigation of tirzepatide” to treat obese or overweight adults.²⁶

53. According to a recent publication, in fall 2022, analysts at UBS projected that Mounjaro could reach peak sales of \$25 billion, asserting Eli Lilly’s position in the multibillion-dollar obesity market.²⁷

54. In March 2023, it was reported that Eli Lilly kicked off a full-scale consumer campaign for Mounjaro after launching a digital campaign in January, including a 75-second TV spot supporting Mounjaro aired on FOX on February 12, the same day as Super Bowl LVII.²⁸

²⁴Bain P, *Ozempic was 2023’s Buzziest Drug*, AdAge (July 10, 2023) available at <https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571> (last visited on 8/24/23).

²⁵ *FDA approves Lilly’s Mounjaro™ (tirzepatide) injection, the first and only GIP and GLP-1 receptor agonist for the treatment of adults with type 2 diabetes*, Cision PR Newswire (May 13, 2022) available at <https://www.prnewswire.com/news-releases/fda-approves-lillys-mounjaro-tirzepatide-injection-the-first-and-only-gip-and-glp-1-receptor-agonist-for-the-treatment-of-adults-with-type-2-diabetes-301547339.html> (last visited on 8/24/23).

²⁶ *Lilly Receives U.S. FDA Fast Track designation for tirzepatide for the treatment of adults with obesity, or overweight with weight-related comorbidities* (October 6, 2022) available at <https://investor.lilly.com/news-releases/news-release-details/lilly-receives-us-fda-fast-track-designation-tirzepatide> (last visited on 8/24/23).

²⁷ Munger L, BioSpace, *Eli Lilly and Novo Nordisk Face Off in Lucrative Obesity Market* (May 30, 2023) available at <https://www.biospace.com/article/eli-lilly-and-novo-nordisk-face-off-in-lucrative-obesity-market/> (last visited on 8/24/23).

²⁸ O’Brien J, Medical Marketing and Media, *Eli Lilly kicks off consumer campaign for diabetes drug Mounjaro* (March 9, 2023) available at <https://www.mmm-online.com/home/channel/campaigns/eli-lilly-kicks-off-consumer-campaign-for-diabetes-drug-mounjaro/> (last visited on 8/24/23).

55. On April 11, 2023, the New York Times reported that Mounjaro was “gaining attention, with many people using it off-label to lose weight.” The article described research which “found that Mounjaro may be even more powerful” than Ozempic, which it reported had recently “steamrolled through TikTok, talk shows and tabloids as people raved about using it off-label to lose weight.” Although Eli Lilly denied promoting or encouraging “the off-label use of any of our medicines[,]” it was obvious to Eli Lilly and others in the industry that Mounjaro was following Ozempic’s rising popularity for its weight loss effects. Furthermore, the same article also noted Eli Lilly’s October announcement regarding the FDA’s fast-track designation for its review of tirzepatide.²⁹

C. Defendants’ Drugs Delay Gastric Emptying

56. Semaglutide belongs to a class of medications known as glucagon-like peptide-1 receptor agonists (GLP-1 RAs).³⁰

57. Tirzepatide is also a GLP-1 RA medication in addition to being a glucose-dependent insulintropic polypeptide (GIP) receptor agonist.³¹

58. GLP-1 RAs mimic the activities of physiologic GLP-1, which is a gut hormone that activates the GLP-1 receptor in the pancreas to stimulate the release of insulin and suppress glucagon.³²

²⁹ Blum D, *The Diabetes Drug That Could Overshadow Ozempic*, The New York Times (published April 11, 2023, updated June 24, 2023) available at <https://www.nytimes.com/2023/04/11/well/live/ozempic-mounjaro-weight-loss-diabetes.html> (last visited on 8/24/23).

³⁰ Smits MM & Van Raalte DH (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563 (last visited on 8/24/23).

³¹ Farzam & Patel, *Tirzepatide*, National Library of Medicine (July 2, 2023), available at <https://www.ncbi.nlm.nih.gov/books/NBK585056/> (last visited 8/24/23).

³² Hinnen D, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) Diabetes Spectr., 202–210 (August 2017) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/> (last visited on 8/24/23).

59. In addition, Defendants knew or should have known from published medical literature that non-pancreatic effects of GLP-1 include slowing of gastric emptying.³³

60. It is well documented in the literature that GLP-1 RAs cause delayed gastric emptying. For example, a study published in October 2017 (before Defendants began marketing and selling their GLP-1 RA drugs) evaluated the effect of GLP-1 RAs on gastrointestinal tract motility and residue rates and explained that “GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region.” The study authors concluded that the GLP-1 RA drug liraglutide “exhibited gastric-emptying delaying effects” and “the drug also inhibited duodenal and small bowel movements at the same time.”³⁴

61. As early as 2010, a study published in *The Journal of Clinical Endocrinology & Metabolism* indicated that that GLP-1 slows gastric emptying.³⁵

62. Defendants knew or should have known of this risk of gastroparesis from the clinical trials.

63. Two subjects in the Wegovy phase 3 trial pool taking semaglutide 2.4 mg reported moderate adverse events of impaired gastric emptying and both subjects permanently discontinued treatment due to the adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376.

³³ Deane AM et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) *J Clinical Endo Metabolism*, 225-221 (January 1, 2010) available at <https://academic.oup.com/jcem/article/95/1/215/2835243> (last visited on 8/24/23); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023) available at <https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery> (last visited on 8/24/23).

³⁴ Nakatani Y et al., *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, 43(5) *Diabetes & Metabolism*, 430-37 (October 2017) available at <https://www.sciencedirect.com/science/article/pii/S1262363617301076> (last visited on 8/24/23).

³⁵ Deane AM et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) *J Clinical Endo Metabolism*, 225-221 (January 1, 2010) available at <https://academic.oup.com/jcem/article/95/1/215/2835243> (last visited on 8/24/23).

64. The cardiovascular outcomes trials for Wegovy included two cases of gastroparesis with the first subject being diagnosed with severe gastroparesis after one month in the trial and second subject being diagnosed with gastroparesis after approximately two months in the trial.

65. Similarly, a phase 1 study of Mounjaro (GPGA) found that tirzepatide delays gastric emptying.

66. On information and belief, Defendants not only knew or should have known that their GLP-1 RA drugs cause delayed gastric emptying with a risk of gastroparesis, but they may have sought out this effect due to its association with weight loss. For example, a recent study published in 2023 notes that “it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying]” and the study authors suggested “further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake.”³⁶

D. The Medical Literature and Clinical Trials Gave Defendants Notice of Gastroparesis Being Causally Associated with Ozempic and Mounjaro

67. Defendants further knew or should have known of the risk of gastroparesis from the published medical literature.

68. In August of 2020, medical literature advised that some “patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose.” The article went on to explain that “[t]his class of drugs can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis.”³⁷

³⁶ Jensterle M et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) *Diabetes Obes. Metab.* 975-984 (April 2023) available at <https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944> (last visited on 8/24/23).

³⁷ Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, *Diabetes Spectr.* (2020), Aug; 33(3): 290–297, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/> (last visited on 8/24/23).

69. In a September 2020 article funded and reviewed by the Novo Nordisk Defendants, scientists affiliated with all Defendants reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes.³⁸ More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% versus placebo (5.7-7.6%) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that “[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when initiating or escalating doses of oral semaglutide.” For patients with other comorbidities, the study warned that “patients should be made aware of the occurrence of gastrointestinal AEs with GLP-1RAs.”

70. A July 2021 article funded and reviewed by the Novo Nordisk Defendants considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that “gastrointestinal disturbances” were “well-known” side effects associated with semaglutide use.³⁹ When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus 8% on the placebo group), vomiting in up to 11.5% of patients (versus 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for GI-related adverse events, with some trials experiencing

³⁸ Mosenzon O, Miller EM, & Warren ML, *Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients*, Postgraduate Medicine (2020), 132:sup2, 37-47, available at DOI:10.1080/00325481.2020.1800286 (last visited on 8/24/23).

³⁹ Smits MM & Van Raalte DH (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563 (last visited on 8/24/23).

100% discontinuation due to GI-related adverse events. The mean value of GR-related adverse events that led to discontinuation averaged 57.75%. Semaglutide appears to be associated with more frequent vomiting and nausea as compared to other GLP-1 RAs. The study acknowledges that while nausea and vomiting are unwanted side effects, “they may be partly responsible for aspects of the drug’s efficacy.”

71. An October 2021 article in the Journal of Investigative Medicine (“JIM”) concluded that because gastroparesis can be associated with several medications, “[i]t is crucial to identify the causative drugs as discontinuation of the drug can result in resolution of the symptoms[.]”⁴⁰ In diabetics, making this determination can be particularly “tricky” because both diabetes and GLP-1 RAs can cause delayed gastric emptying. As such, “the timeline of drug initiation and symptom onset becomes of the utmost importance.” The authors reviewed two case reports (discussed below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis is critical.

72. Case Report #1 in JIM involved a 52-year-old female with long-standing (10 years) well-controlled, type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient was referred with a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient’s stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide and her symptoms resolved after six weeks. The case report authors concluded that “thorough history taking revealed the cause [of gastroparesis] to be medication induced.”⁴¹

⁴⁰ Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/> (last visited on 8/24/23).

⁴¹ Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/> (last visited on 8/24/23).

73. Case Report #2 in JIM involved a 57-year-old female with a long-standing (16 years) type 2 diabetes who had been taking weekly dulaglutide injections (another GLP-1 RA) for 15 months and suffering from abdominal bloating, nausea, and vomiting for 12 of those months. A gastric emptying study showed 35% retention of isotope in the patient's stomach at four hours, indicating delayed gastric emptying. After discontinuing dulaglutide, the patient experienced a gradual resolution of symptoms over a four-week period.⁴²

74. On June 29, 2023, the American Society of Anesthesiologists ("ASA") warned that patients taking semaglutides and other GLP-1 RAs should stop the medication at least a week before elective surgery because these medications "delay gastric (stomach) emptying" and "the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation."⁴³ The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.

75. A July 25, 2023, article in Rolling Stone magazine, "*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'*", highlighted three patients who have suffered severe GI-related events, including gastroparesis, as a result of their use of GLP-1 RAs.⁴⁴ Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded that her problems were caused and/or exacerbated by her use of a GLP-1 RA medication. Patient 2 (female)

⁴² Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/> (last visited on 8/24/23).

⁴³ American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023) available at <https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery> (last visited on 8/24/23).

⁴⁴ Jones CT, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'*, Rolling Stone (July 25, 2023) available at <https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601> (last visited on 8/24/23).

used Ozempic for one year and reported incidents of vomiting, including multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1 RA. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1s, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1s are known to cause a delay in gastric emptying, ... [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about gastroparesis.

76. On July 25, 2023, CNN reported that patients taking Ozempic have been diagnosed "with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic."⁴⁵ Additionally, "[t]he US Food and Drug Administration said it has received reports of people on the drugs experiencing stomach paralysis[.]"

77. Upon information and belief, Defendants knew or should have known of the causal association between the use of GLP-1 RAs and the risk of developing gastroparesis. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, medical literature, including the medical literature and case reports referenced above in this Amended Complaint.

78. Upon information and belief, Defendants ignored the causal association between the use of GLP-1 RAs and the risk of developing gastroparesis.

⁴⁵ Goodman B, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN Health (July 25, 2023) available at <https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis> (last visited on 8/24/23).

79. Defendants’ failure to disclose information that they possessed regarding the causal association between the use of GLP-1 RAs and the risk of developing gastroparesis, rendered the warnings for their medications inadequate.

E. Defendants Failed to Warn of the Risk of Gastroparesis From Ozempic and Mounjaro

80. Gastroparesis is a disorder that slows or stops the movement of food from the stomach to the small intestine, even though there is no blockage in the stomach or intestines. Gastroparesis may also be called delayed gastric emptying.⁴⁶

81. Symptoms of gastroparesis include nausea, vomiting, early satiation, postprandial fullness, bloating, and upper abdominal pain, which can be refractory and challenging to manage, leading to reduced quality of life and significant health care expenditure.⁴⁷

82. The Novo Nordisk Defendants’ main promotional website for Ozempic (ozempic.com) includes a variety of information about the benefits of Ozempic relating to blood sugar, cardiovascular health, and weight loss, as well as “Important Safety Information” – however, Defendants do not disclose any risks causally associated with gastroparesis within the “Important Safety Information” section of their promotional website.

83. Similarly, the Prescribing Information discloses warnings, precautions, and adverse reactions causally associated with Ozempic, but it does not disclose the risk of gastroparesis. Instead, it discloses delayed gastric emptying under the “Drug Interaction” heading and notes that Ozempic “may impact absorption of concomitantly administered oral medications.” Further, under the “Mechanism of Action” section, the Prescribing Information states that “[t]he mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial

⁴⁶Camilleri M, National Institute of Diabetes and Digestive and Kidney Diseases, *Gastroparesis*, available at <https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis> (last visited on 8/24/23).

⁴⁷ Zheng T, Camilleri M, *Management of Gastroparesis*, *Gastroenterology & Hepatology* (Nov. 2021), Vol. 17, Issue 11, available at <https://www.gastroenterologyandhepatology.net/archives/november-2021/management-of-gastroparesis/> (last visited on 8/24/23).

phase.”⁴⁸ These statements do not disclose gastroparesis as a *risk* of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

84. None of Defendants’ additional advertising or promotional materials warned prescription providers or the general public of the risk of gastroparesis.

85. News sources have identified the potential for serious side effects in users of Ozempic and Mounjaro, including chronic motion sickness, leading to hospitalization.⁴⁹ For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable.⁵⁰ One user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had “vomited so much that [she] didn’t have the energy to get up.”⁵¹ CNN recently reported that an Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.⁵²

86. As noted above, as early as 2020, studies conducted on the safety of semaglutide identified the prevalence of gastrointestinal adverse effects, including nausea and vomiting. One study reported that gastrointestinal complaints are the main adverse-event related cause of drug discontinuation in phase-3 trials, suggesting that these “common side effects” are severe and persistent.⁵³

⁴⁸ Ozempic prescribing information, available at <https://www.novo-pi.com/ozempic.pdf> (last visited on 8/24/23).

⁴⁹ Min P, *Ozempic May Cause Potential Hospitalizations*, healthnews (June 26, 2023) available at <https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/> (last visited on 8/24/23).

⁵⁰ Nelson EL, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023) available at <https://bestlifeonline.com/ozempic-side-effects-news/> (last visited on 8/24/23).

⁵¹ Bendix A, Lovelace B Jr., *What it’s like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023) available at <https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493> (last visited on 8/24/23).

⁵² Goodman B, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN (July 25, 2023) <https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis/index.html> (last visited on 8/24/23).

⁵³ Mosenzon O, Miller EM, & Warren ML (2020) Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients, *Postgraduate Medicine*, 132:sup2, 37-47, DOI:10.1080/00325481.2020.1800286 (last visited on 8/24/23); *see also* Smits, MM & Van Raalte, DH (2021), *Safety of Semaglutide*, *Front. Endocrinol.*, 07 July 2021, doi: 10.3389/fendo.2021.645563 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/> (last visited on 8/24/23).

87. Studies also identified a link between nausea induced by GLP-1RAs and weight loss, leading some authors to suggest that nausea and vomiting may play a role in the drug's efficacy.⁵⁴

88. The Ozempic label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic patients but does not include vomiting in its "Warnings and Precautions" section, and it does not indicate a severity of risk. Gastroparesis is not mentioned at all.

89. In January 2020, Novo Nordisk Defendants removed the "Instructions" portion from Section 17 "Patient Counseling Information" of the Ozempic label, which had instructed prescribers to "[a]dvice patients that the most common side effects of Ozempic are nausea, vomiting, diarrhea, abdominal pain and constipation." These instructions were present in the 2017 and 2019 labels.

90. The Mounjaro label lists nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain as common adverse reactions, but it does not indicate a severity of symptoms. Even though the label warns about the risk of Severe Gastrointestinal Disease, gastroparesis is not specifically mentioned.

91. In its section on "Females and Males of Reproductive Potential," the Ozempic label advises women users to discontinue Ozempic at least 2 months before a planned pregnancy due to the long washout period for semaglutide. This demonstrates that Novo Nordisk Defendants knew or should have known that symptoms, such as continuous and violent vomiting, can linger long after the drugs are discontinued and shows the need to warn of gastroparesis.

92. From the date the Novo Nordisk Defendants received FDA approval to market Ozempic until the present time, the Novo Nordisk Defendants made, distributed, marketed, and/or

⁵⁴ *Id.*

sold Ozempic without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Ozempic was causally associated with and/or could cause gastroparesis.

93. From the date Eli Lilly received FDA approval to market Mounjaro until the present time, Eli Lilly made, distributed, marketed, and/or sold Mounjaro without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Mounjaro was causally associated with and/or could cause gastroparesis.

94. Upon information and belief, Defendants knew or should have known of the causal association between the use of GLP-1 RAs and the risk of developing gastroparesis. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced above in this Complaint.

95. Upon information and belief, Defendants ignored the causal association between the use of GLP-1 RAs and the risk of developing gastroparesis.

96. Defendants' failure to disclose information that they possessed regarding the causal association between the use of GLP-1 RAs and the risk of developing gastroparesis, rendered the warnings for this medication inadequate.

97. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

FIRST CAUSE OF ACTION
(INADEQUATE WARNING UNDER LA. R.S. 9:2800.57 –
AGAINST ALL DEFENDANTS)

98. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

99. Louisiana law imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when producing, manufacturing, distributing, leasing, and selling their products.

100. At all times mentioned herein, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Ozempic and Mounjaro that were used by the Plaintiff.

101. Ozempic and Mounjaro were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by the Defendants.

102. At all relevant times, and at the times Ozempic and Mounjaro left the Defendants' control, Defendants knew or should have known that Ozempic and Mounjaro were unreasonably dangerous because they did not adequately warn of the risk of gastroparesis, especially when used in the form and manner as provided by Defendants.

103. Despite the fact that Defendants knew or should have known that Ozempic and Mounjaro caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell Ozempic and Mounjaro to consumers, including Plaintiff, without adequate warnings.

104. Despite the fact that Defendants knew or should have known that Ozempic and Mounjaro caused unreasonably dangerous injuries, Defendants continued to market Ozempic and Mounjaro to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

105. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

106. At all relevant times, given their increased safety risks, Ozempic and Mounjaro were not fit for the ordinary purpose for which they were intended—namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

107. At all relevant times, given their increased safety risks, Ozempic and Mounjaro did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff.

108. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Ozempic and Mounjaro into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis.

109. At all relevant times, Plaintiff was using Ozempic and Mounjaro for the purposes and in a manner normally intended—namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

110. The Ozempic and Mounjaro designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the products created a risk of serious and dangerous injuries, including gastroparesis, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

111. The Ozempic and Mounjaro designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to

inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including gastroparesis, as well as other severe and permanent health consequences from Ozempic and Mounjaro, they failed to provide adequate warnings to users and/or prescribers of the product, and continued to improperly advertise, market and/or promote their products, Ozempic and Mounjaro.

112. The labels for Ozempic and Mounjaro were inadequate because they did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic and Mounjaro, including the increased risk of gastroparesis.

113. The labels for Ozempic and Mounjaro were inadequate because they did not warn and/or adequately warn that Ozempic and Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis.

114. The labels for Ozempic and Mounjaro were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Ozempic and Mounjaro.

115. The labels for Ozempic and Mounjaro were inadequate because they did not warn and/or adequately warn of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects.

116. Communications made by Defendants to Plaintiff and her prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic and Mounjaro, including the increased risk of gastroparesis.

117. Communications made by Defendants to Plaintiff and her prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Ozempic and

Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis.

118. Plaintiff had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and her reliance upon Defendants' warnings was reasonable.

119. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and his/her/their reliance upon Defendants' warnings was reasonable.

120. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of gastroparesis causally associated with Ozempic and Mounjaro, he/she/they would not have prescribed Ozempic and Mounjaro and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic and Mounjaro so as to allow Plaintiff to make an informed decision regarding her use of Ozempic and Mounjaro.

121. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Ozempic and Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, he/she/they would not have prescribed Ozempic and Mounjaro and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic and Mounjaro so as to allow Plaintiff to make an informed decision regarding her use of Ozempic and Mounjaro.

122. Had Plaintiff been warned of the increased risk of gastroparesis causally associated with Ozempic and Mounjaro, she would not have used Ozempic and Mounjaro and/or suffered from gastroparesis and its sequelae.

123. Had Plaintiff been warned that Ozempic and Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, she would not have used Ozempic and Mounjaro and/or suffered gastroparesis and its sequelae.

124. Had Plaintiff been warned of the increased risk of gastroparesis causally associated with Ozempic and Mounjaro, she would have informed her prescribers that she did not want to take Ozempic or Mounjaro.

125. Upon information and belief, if Plaintiff had informed her prescribing physician(s) that she did not want to take Ozempic or Mounjaro due to the risk of gastroparesis, her prescribing physician(s) would not have prescribed Ozempic and Mounjaro.

126. By reason of the foregoing, Defendants have become liable to the Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, Ozempic and Mounjaro.

127. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by the Plaintiff in accordance with LA R.S. 9:2800.57.

128. Defendants' inadequate warnings of Ozempic and Mounjaro were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

129. That said inadequate warnings in Defendants' drugs Ozempic and Mounjaro were a substantial factor in causing Plaintiff's injuries.

130. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

131. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that she will require future medical and/or hospital care, attention, and services.

SECOND CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY UNDER LA. R.S. 9:2800.58 –
AGAINST ALL DEFENDANTS)

132. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

133. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic and Mounjaro as hereinabove described that was used by Plaintiff.

134. At all relevant times, Defendants expressly warranted to Plaintiff and her prescribing physician(s) that Ozempic and Mounjaro were safe as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

135. The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician by way of Ozempic's and Mounjaro's labels, websites, advertisements, promotional materials, and through other statements.

136. As a result of Defendants' express warranties to her prescribing physician(s), he/she/they were induced to prescribe Ozempic and Mounjaro to Plaintiff, and Plaintiff was induced to use Ozempic and Mounjaro.

137. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as the Plaintiff, would use and/or consume Ozempic and Mounjaro based upon their express warranties.

138. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as the Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Ozempic and Mounjaro based upon their express warranties.

139. At all relevant times, Defendants knew or should have known that Ozempic and Mounjaro were unreasonably dangerous because of their increased risk of gastroparesis, especially when the drugs were used in the form and manner as provided by Defendants.

140. At all relevant times, Defendants knew or should have known that Ozempic and Mounjaro had not been sufficiently and/or adequately tested for safety.

141. The unreasonably dangerous characteristics of Ozempic and Mounjaro were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drugs' characteristics.

142. The unreasonably dangerous characteristics of Ozempic and Mounjaro were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.

143. At the time Ozempic and Mounjaro left the Defendants' control, Ozempic and Mounjaro did not conform to Defendants' express warranties because Ozempic and Mounjaro were not safe to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, in that they were causally associated with an increased risk of gastroparesis.

144. The express warranties made by Defendants regarding the safety of Ozempic and Mounjaro were made with the intent to induce Plaintiff to use the products and/or her prescribing physician(s) to prescribe the products.

145. Defendants knew and/or should have known that by making the express warranties to Plaintiff and/or her prescribing physician(s) it would be the natural tendency of Plaintiff to use Ozempic and Mounjaro and/or the natural tendency of her prescribing physician(s) to prescribe Ozempic and Mounjaro.

146. Plaintiff and her prescribing physician(s), as well as members of the medical community, relied on the express warranties of the Defendants identified herein.

147. Had Defendants not made these express warranties, Plaintiff would not have used Ozempic and Mounjaro and/or, upon information and belief, her prescribing physician(s) would not have prescribed Ozempic and Mounjaro.

148. Plaintiff's injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.

149. Plaintiff's injuries and damages arose from a reasonably anticipated use of the products by Plaintiff.

150. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff.

151. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

152. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Ozempic and Mounjaro drugs.

153. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that she will require future medical and/or hospital care, attention, and services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff, JACLYN BJORKLUND, for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, JACLYN BJORKLUND, health care costs, medical monitoring, together with interest and costs as provided by law;
2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff, JACLYN BJORKLUND, in an amount sufficient to punish Defendants and deter future similar conduct;
3. Awarding Plaintiff, JACLYN BJORKLUND, reasonable attorneys' fees;
4. Awarding Plaintiff, JACLYN BJORKLUND, the costs of these proceedings; and
5. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: August 25, 2023

By: /s/ Rene F. Rocha
Rene F. Rocha

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**Application for admission pro hac vice to
be filed*